

# Exhibit A

**UNITED STATES DISTRICT COURT**  
**FOR THE DISTRICT OF NEW JERSEY**

**IN RE: VALSARTAN PRODUCTS  
LIABILITY LITIGATION**

**CIVIL ACTION NUMBER:**

**19-md-02875-RBK-JS**

**STATUS CONFERENCE**

Mitchell H. Cohen Building & U.S. Courthouse  
4th & Cooper Streets  
Camden, New Jersey 08101  
August 14, 2019  
Commencing at 2:09 p.m.

**B E F O R E:**

**THE HONORABLE JOEL SCHNEIDER,  
UNITED STATES MAGISTRATE JUDGE**

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1 (PROCEEDINGS held in open court before The Honorable Joel  
2 Schneider, United States Magistrate Judge, at 2:09 p.m.)

3 THE COURT: Good afternoon, everyone. Please be  
4 seated. Welcome.

5 We are on the record in the Valsartan matter, Docket  
6 Number 19-2875.

7 I would just ask whoever is going to speak for the  
8 parties, if you could jut say your name so the court reporter  
9 knows who's talking.

10 I just want to let you know at approximately 3:00,  
11 we'll have to take a short break for a short criminal  
12 proceeding. It just came in. It won't take long, but it's  
13 something we have to do. But I didn't want to hold this up,  
14 so we'll just get going. Okay?

15 I have your letters. I read your letters, of course.  
16 If, as I predict correctly, you made some progress in the  
17 morning when you met and conferred, and we'll talk about that.

18 Two general issues to talk about today: The core  
19 discovery disputes and the insurance disclosure disputes, but  
20 before that, I just want to see if we can just address a  
21 couple of housekeeping matters.

22 The service on the companies pursuant to the Hague,  
23 is that done or close to being done?

24 MS. GOLDENBERG: This is Marlene Goldenberg for the  
25 plaintiffs. And we, unfortunately, are still roughly in the

1 same place that we were last month. When we contacted the  
2 agencies about starting international process service, they  
3 told us that their time estimate was close to a year for most  
4 of the entities. So, you know, they've -- the wheels are in  
5 motion and things are going as quick as we can, but it gets a  
6 bit out of our hands at this point.

7 THE COURT: Which are the companies again that have  
8 to be served?

9 MS. GOLDENBERG: It's generally the four API  
10 manufacturers, so it's the Aurobindo API, the Mylan API -- if  
11 I'm getting any of this wrong, please someone correct me --  
12 and I think --

13 MR. SLATER: Hetero.

14 MS. GOLDENBERG: Hetero, as well.

15 THE COURT: So, I know we have ZHP is an API  
16 manufacturer. Are they the only API manufacturer who is in  
17 the case now at the moment?

18 MR. SLATER: Torrent is basically in. We have an  
19 agreement that we just have to formalize something, but they  
20 have agreed to be in and they'll accept service.

21 THE COURT: They are an API manufacturer?

22 MS. BRANCATO: Your Honor, this is Alexia Brancato on  
23 behalf of Torrent.

24 MR. SLATER: Oh, I didn't realize you said API. I  
25 just thought we were talking about --

1 THE COURT: Yes, just talking about API.

2 Is ZHP the only API manufacturer who is in the case?

3 MS. GOLDENBERG: Yes.

4 MR. HONIK: That's right.

5 THE COURT: Okay. So it's out of your hands; you  
6 just have to wait for the authorities to do what they have to  
7 do?

8 MS. GOLDENBERG: Unfortunately, yes.

9 THE COURT: Okay. Everything on track for the MDL  
10 application in September?

11 MR. HONIK: Yes. We anticipate that will be on file  
12 sometime next week.

13 THE COURT: Okay. And --

14 MR. HONIK: Yes.

15 THE COURT: So by now you probably know what you're  
16 going to ask for. You're going to ask for the addition of the  
17 third chemical and all sartans; am I right about that?

18 MR. HONIK: The last -- Judge, the last draft of it  
19 that I saw just included losartan and irbesartan. You raise a  
20 good question about whether it should speak to the new  
21 chemical. We'll certainly --

22 THE COURT: I thought we talked about this the last  
23 time.

24 MR. HONIK: I apologize. I was not here at the last  
25 case management conference, but we'll confer internally.

1           THE COURT: My recollection is -- the record will  
2 speak for itself -- that the application was going to be for  
3 all sartans and not just the two you mentioned. Am I wrong  
4 about that?

5           MR. SLATER: That was the discussion, your Honor, to  
6 capture any contaminated sartans, any sartans with a  
7 contamination.

8           THE COURT: But I just want to know what's going to  
9 be presented to the panel.

10          MR. HONIK: We'd like to style it in a way that  
11 captures all contaminated sartans.

12          THE COURT: Okay. I spoke to Judge Kugler. He's out  
13 this week in Washington, saving us from terrorists. He's  
14 going to respond to the motion-to-dismiss letters next week,  
15 he said, when he gets back.

16          My notes indicate the short-form complaint was due I  
17 think today, so we'll get that and we'll enter that. Am I  
18 right about that?

19          MS. GOLDENBERG: Yes, your Honor. You have it in  
20 your e-mail, I hope. Otherwise, I'm happy to send it again.

21          THE COURT: Today?

22          MS. GOLDENBERG: I'm sorry?

23          THE COURT: When was it sent?

24          MS. GOLDENBERG: During -- or right before the last  
25 hearing. I'm happy -- I can send it again.

1 THE COURT: The final version?

2 MS. GOLDENBERG: Yes. But, actually, in light of the  
3 order that you issued over lunch where you renumbered the case  
4 management orders, I was going to point out that it now needs  
5 to be CMO 12 anyway --

6 THE COURT: I'll change that.

7 MS. GOLDENBERG: -- so I'll resend it.

8 THE COURT: Okay. Could you do me a favor, resend  
9 it? I don't recollect seeing that.

10 MS. GOLDENBERG: Not a problem, yes.

11 THE COURT: That's why it hasn't been entered yet.

12 Okay. And I know the defendants are concerned about  
13 this. Are we on track to finalize the plaintiffs' fact sheets  
14 by the end of the month?

15 MS. LOCKARD: Yes, your Honor. Victoria Lockard for  
16 Teva and the Executive Committee. We are on track. We  
17 anticipate submitting a finalized version next week that  
18 incorporates your Honor's rulings.

19 THE COURT: Terrific.

20 MS. LOCKARD: If we can get that entered and set the  
21 clock running on the target date of August 28th, I think  
22 that's what we anticipate. And then it's just a matter of how  
23 much time the plaintiffs would be allowed to respond. At the  
24 last conference, we proposed 30 days, and then there was some  
25 discussion for a little longer. Has your Honor come to any

1 conclusion on that?

2 THE COURT: Well, I know 30 days is too short. What  
3 did we do in Benicar? Was it 60 or 90 days? I don't  
4 remember.

5 MR. PAREKH: Your Honor, for the initial set, it was  
6 90, and then it was 60 going forward. So for people who had  
7 filed as of prior to the date the PFS was entered, they got 90  
8 days to respond, and then anybody who filed after that point  
9 had 60 days from, I believe, the initial service of the  
10 complaint.

11 THE COURT: Okay. Do you have any objection to that?

12 MS. LOCKARD: So, we have right now -- I don't know  
13 how many plaintiffs there were pending at that time in the  
14 Benicar MDL. We have, I think, around 125 cases currently in  
15 the MDL; not all of those are personal injury cases. So,  
16 given the -- which I believe is a smaller number, we would --  
17 we would expect that that could be completed in 60 days in  
18 this case, and then going forward 60 days as well, just  
19 because I think we're at the outset of this litigation, and so  
20 the numbers -- the short form, for example, hasn't been  
21 entered, so we don't have a backlog of plaintiffs, you know,  
22 500, 600 plaintiffs that this needs to be completed for.

23 THE COURT: Let's go with the 90/60. I don't think  
24 the defendants are going to be prejudiced in any material  
25 respect. I'll dig out the Benicar order and basically enter

1 the same language that we entered there. It worked well. And  
2 we'll probably also mirror the same order-to-show-cause  
3 procedure we used which worked so well in Benicar, that  
4 protects your interests, and we'll get the ball rolling on  
5 plaintiffs' discovery.

6 MS. LOCKARD: Okay. We'll submit a proposed order  
7 then, along with the plaintiff fact sheet, that incorporates  
8 that procedural process for the show cause.

9 Now, with just one point of clarification. So what  
10 we're submitting in our -- certainly, will get entered -- is  
11 the personal injury plaintiffs' fact sheets --

12 THE COURT: Yes.

13 MS. LOCKARD: -- so there are additional for medical  
14 monitoring, consumer fraud plaintiffs, and the TPP plaintiffs,  
15 which we need a little more time to --

16 THE COURT: The class reps.

17 MS. LOCKARD: -- finalize the reps.

18 THE COURT: Just the class reps, right?

19 MS. LOCKARD: Right. So that will be a separate  
20 submission.

21 THE COURT: No problem.

22 MS. LOCKARD: But we would like to get the personal  
23 injury rolling.

24 THE COURT: Yes, no problem.

25 MS. LOCKARD: Thank you.

1 THE COURT: Okay. So you'll prepare the order, a  
2 draft order that accompanies the fact sheet?

3 MS. LOCKARD: Yes.

4 THE COURT: Okay. And I'm sure you'll run it by  
5 plaintiffs, and if you just mirror Benicar, that's fine with  
6 us.

7 MS. LOCKARD: Understood.

8 THE COURT: Okay. I think those are the background  
9 issues I wanted to cover.

10 So two general issues: The core discovery and the  
11 insurance disclosure.

12 And, as I see it, the core discovery is divided into  
13 two parts, what I call the macro issues, the issues that apply  
14 to all defendants, and then there may be issues specific to  
15 particular defendants. Why don't we deal with what I call the  
16 macro issues, the issues, disputes, et cetera, that apply to  
17 all the defendants.

18 Plaintiff, you raised the dispute. We'll hear from  
19 the defendants and we'll see if we can get it resolved. I  
20 have all the papers in front of me.

21 MR. SLATER: Maybe the first thing to do would be to  
22 confirm what we discussed before we came in, probably make  
23 sense, right?

24 MR. GOLDBERG: Sure.

25 MR. SLATER: I'll try to recite it, if you want, and

1 you guys can correct me if I miss anything.

2 We had a good meeting today in the morning, your  
3 Honor, here in the courtroom. Thank you for letting us have  
4 the courtroom. It was very helpful. And then we spoke a  
5 little after lunch, based on the discussion.

6 So, I think we've reached agreement that -- and these  
7 agreements apply to the core-discovery defendants -- the API  
8 manufacturers, the finished dose manufacturers, correct?  
9 That's the scope of what we're talking about, right?

10 THE COURT: Can I just proceed for one moment? I  
11 tried to straighten out who belongs in which category. For  
12 the API manufacturers and suppliers, I have -- and I'm not  
13 going to give the whole corporate name -- ZHP, Hetero, Mylan,  
14 and Aurobindo. Is there anyone else besides those four?

15 MR. SLATER: I don't believe so.

16 THE COURT: Okay. For the finished product/dose  
17 manufacturers, I have Teva and Torrent. Did I miss anyone?

18 MS. HEINZ: Yes. Aurolife.

19 THE COURT: Aurolife?

20 MS. HEINZ: Aurolife Pharma LLC.

21 THE COURT: Okay. Is that with an A?

22 MS. HEINZ: Yes.

23 THE COURT: Okay. Aurolife is a finished --

24 MS. HEINZ: Jessica Heinz. I apologize, your Honor.

25 THE COURT: Okay. They are in the finished dose

1 category?

2 MS. HEINZ: They are a finished dose.

3 MS. LOCKARD: And, your Honor, Actavis is a related  
4 Teva entity, also finished dose. I just want to make sure  
5 that's -- that's within the Teva umbrella.

6 MS. GOLDENBERG: If you want, your Honor, I've got a  
7 full list of everyone.

8 THE COURT: Why don't you give it to me?

9 MS. GOLDENBERG: Okay.

10 THE COURT: Read it out.

11 MS. GOLDENBERG: So the APIs you correctly  
12 identified -- Aurobindo Pharma Limited, Hetero Drugs Limited,  
13 Hetero Labs -- I'm sorry. Hetero Drugs Limited is the API  
14 manufacturer parent corporation. The API manufacturer is  
15 Hetero Labs Limited. Mylan Laboratories Limited is an API.  
16 ZHP Limited is a manufacturer -- is an API manufacturer, and  
17 that's that group.

18 For finished dose manufacturers, we have Arrow Pharm  
19 (Malta) Limited.

20 THE COURT: Arrow Pharm?

21 MS. GOLDENBERG: Yes.

22 THE COURT: Is that different than Aurolife?

23 MS. GOLDENBERG: It is.

24 Aurolife Pharma LLC is also a finished dose  
25 manufacturer. Hetero Labs Limited is a finished dose. Mylan

1   Pharmaceuticals, Incorporated.   Teva Pharmaceutical -- I'm  
2   sorry -- Teva Pharmaceutical Industries Limited.   Torrent  
3   Pharmaceuticals Limited.   ZHP is both an API and a finished  
4   dose manufacturer, so they fall into both categories.   And I  
5   think that covers everyone of each.

6           THE COURT:   So some defendants in the corporate chain  
7   might be in both categories?

8           MS. GOLDENBERG:   I believe ZHP is the only one that  
9   falls into both, but yes.   Oh, and Hetero Labs.   Sorry.

10          THE COURT:   Have all the finished product defendants,  
11   have they all been served?

12          MS. POLETTTO:   Hetero Labs Limited has not.

13          THE COURT REPORTER:   I'm sorry.   Your name?

14          MS. POLETTTO:   Janet Poletto.

15          THE COURT:   Are they a foreign company?

16          MS. POLETTTO:   Yes, your Honor.

17          THE COURT:   Anyone else in the finished product  
18   category?

19          MR. SLATER:   Now my comment on Torrent would be  
20   relevant.   I think we have an agreement on it.   We're just  
21   putting some fine touches on it.   But there is agreement that  
22   there is not going to be a service issue as to them.   They  
23   haven't been served yet, but there is no issue with that.

24          MS. LOCKARD:   And I believe Arrow (Malta) hasn't been  
25   served yet either, but they're no longer an extant company, so

1 that they just don't exist anymore.

2 THE COURT: Okay. All right. I think I interrupted  
3 you, Mr. Slater, so the floor is yours.

4 MR. SLATER: No problem.

5 So we have agreement, again, for I guess those two  
6 groups of defendants that we just identified, because they're  
7 the ones that are subject to the core discovery, that they  
8 will each provide -- or to the extent that I guess we're going  
9 to get a letter from all the defendants listing all of the API  
10 and finished dose manufacturing facilities, so that we will  
11 have those lists so we will be able to cross-reference them to  
12 other discovery, know where everything --

13 THE COURT: Could you be a little bit more specific?  
14 Is it going to be just for valsartan or the all sartans or is  
15 it different?

16 MR. SLATER: The only discussion we had was revolving  
17 around valsartan, and that's all that's been committed to by  
18 the defendants. I'm not in a position today to advocate for  
19 anything beyond that. You are. I'm not.

20 THE COURT: Okay. It's the API manufacturing  
21 facilities?

22 MR. SLATER: The API manufacturing facilities and the  
23 finished drug or finished dose manufacturing facilities.

24 THE COURT: Okay. So that would be -- clearly,  
25 that's relevant. That were involved with what? The recalls?

1 Or just made it at any time?

2 MR. SLATER: At any time, I think, and then, you  
3 know, I guess as we go through the case, we'll figure out  
4 which facilities are implicated.

5 THE COURT: They might be the same; they might not be  
6 the same?

7 MR. SLATER: Right.

8 THE COURT: Okay. So do we have to go through the  
9 same exercise if the definition, scope of the case is modified  
10 to include the other sartans or is it likely they're the same  
11 facilities?

12 MR. SLATER: I can't comment. I don't know. I'm  
13 sure there is some overlap and probably some difference, but  
14 the defense would know far better than we do.

15 THE COURT: We'll cross that bridge when we come to  
16 it, right? Okay.

17 MR. SLATER: So that was one agreement.

18 And the second one, again, as to the core discovery,  
19 defendants have agreed that they will provide us corporate  
20 organization information, and what we discussed was -- we  
21 discussed corporate organization internal to the company, like  
22 for example, take ZHP as the example. Within the company,  
23 although we didn't get into the details of that, probably have  
24 to discuss more, and obviously that's going to be part of our  
25 discovery requests anyway, our requests for documents, but the

1 more -- the more focused part of the conversation was we're  
2 going to be given corporate organization between the  
3 core-discovery defendants, the API and finished dose  
4 manufacturers, and their affiliates that were involved with  
5 the manufacture or sale or distribution of the valsartan, so  
6 that we will know, at least at that level, who is who, who did  
7 what. And they're actually going to -- they have committed to  
8 provide us what is the corporate relationship, for example, is  
9 it a subsidiary, and what their role was in the valsartan  
10 story.

11 THE COURT: Terrific.

12 MR. SLATER: Did they manufacture, did they  
13 distribute, did they package, whatever they did, did they  
14 sell, and we thought that was helpful. And in that context,  
15 they said we will get a list of all the ANDAs because they  
16 will tell us who owns each of the ANDAs as they go through  
17 that list of core-discovery defendants and their affiliates,  
18 so that they will make sure all the ANDAs are accounted for.

19 THE COURT: Which ANDAs?

20 MR. GOLDBERG: Again, valsartan.

21 MR. SLATER: For valsartan. And we discussed this a  
22 little bit. I believe it was agreed, the various valsartan  
23 drugs, not just valsartan. There is valsartan, amlodipine,  
24 hydrochlorothiazide. There is a couple of different  
25 formulations, but they all have a core of valsartan.

1 I think that's the -- that covers the agreements.  
2 I'll leave it to the defense to put a fine point on it, if  
3 necessary.

4 THE COURT: Well, I think that's great because I  
5 would definitely put all of that in the core category, and  
6 that is going to be an immense help to plaintiffs to properly  
7 frame their discovery, so that's perfect.

8 MR. SLATER: Not to the parts we didn't agree to?

9 THE COURT: (Laughs.)

10 MR. SLATER: One of the general issues that we  
11 discussed is -- and it was something that came from some of  
12 the e-mails with the Court, and we have discussed it with the  
13 defense, is to identify which defendants no production has  
14 been made from and why, and that goes to the custody,  
15 possession, control issue. And from our discussions, it  
16 appears that the two foreign defendants for which no  
17 production has been made are Aurobindo and Hetero, and I guess  
18 it's Hetero Labs Limited and Aurobindo -- I don't remember  
19 what comes after Aurobindo, but it's the Indian Aurobindo  
20 entity. Those are the --

21 MS. GOLDENBERG: Aurobindo Pharma Limited.

22 MR. SLATER: Aurobindo Pharma Limited.

23 THE COURT: These are the API manufacturers?

24 MR. SLATER: Yes. And Hetero is also, as we were  
25 just discussing, also a finished dose manufacturer as well.

1           And we discussed with counsel for the U.S. entities,  
2   who are here before the Court, for example, have you tried to  
3   get the documents from them; if somebody in your company were  
4   to send an e-mail and say, hey, send me the test results, can  
5   I take a look at them, would they do it? The conversation  
6   didn't really advance very far, so we're -- I think that's  
7   really as far as we've gotten, that there is no production  
8   from those entities, and at this point I don't think there is  
9   any contemplation -- and, of course, correct me if I'm  
10   wrong -- that there is any contemplation on the defense side  
11   of making a production for them until they're served.

12           THE COURT: Okay. So let's just see if we got this  
13   right, and I don't know the technical legal names of the  
14   companies, but the foreign API manufacturers, Aurobindo,  
15   Hetero, we know they haven't been served pursuant to the  
16   Hague, but do they both have -- I don't know what to call  
17   them -- American affiliates or American subsidiaries?

18           MR. SLATER: Yes, and both are before this Court.

19           THE COURT: Okay. So the legal issue would be do the  
20   American companies have "control" over the foreign companies'  
21   documents such that they can request them and the Court can  
22   order them to be produced?

23           MR. SLATER: That's our understanding, your Honor.

24           THE COURT: That's the legal issue.

25           So, we have, I guess, two choices. You can pursue

1 that avenue against the American companies now or wait until  
2 the foreign companies are served, and then they'll be subject  
3 to court jurisdiction and we can order them to produce them.

4 Defendants, what's your position?

5 MS. POLETTTO: If I may, Your Honor, Janet Poletto for  
6 Hetero U.S.A.

7 Our position is that we are really not in a position  
8 to do any more than we have which, quite honestly, is quite  
9 substantial. We have made a substantial production of  
10 everything that Hetero USA has in its possession that relate  
11 to the ANDAs and any communications with the FDA, and there is  
12 a lot of materials in there. I believe it's close to 30,000  
13 pages of documents that my client has incurred the expense of  
14 doing.

15 It is not really accessible to us in any easy way to  
16 go the next step that apparently the Court is asking. So I  
17 think it would be a burden to place on them during core  
18 discovery. They've got a lot of information in what we've  
19 produced that I think would be very helpful to the plaintiffs,  
20 and we've followed your Honor's order in doing that. But we  
21 don't believe we need to be put in a position of somehow being  
22 forced to try and get this from an entity that we do not  
23 represent, and that, yes, our company is an affiliate  
24 subsidiary, but it's a very -- it has a very limited role in  
25 what it does as the FDA liaison. So we have really extended

1 ourselves significantly at this point.

2 THE COURT: I don't know if the plaintiffs have had  
3 sufficient time to look at all the documents yet, but the  
4 documents you have received from Hetero, do they reflect  
5 communications with the foreign entity and do you have any  
6 sense at the moment whether the production evidences that at  
7 least there is a colorable argument that Hetero has control  
8 over the foreign entity?

9 MR. SLATER: Well, there is certainly a colorable  
10 argument because Hetero USA represents that it is the U.S.  
11 representative of the foreign entity. So the way these  
12 companies work, they're probably -- they're talking all day  
13 long, they're in touch with each other all day. It would be  
14 inconceivable that there is not a free flow of information  
15 between the companies. You know, counsel could correct me,  
16 but it couldn't -- it's inconceivable that, especially where  
17 the USA entity has documents that show they're actually in  
18 business, they're actually operating, and, obviously, we need  
19 what the foreign entity has, it would seem to us that in terms  
20 of the standard, which your Honor actually cited in your --  
21 you've cited previously in the court for us, it would seem to  
22 us they have at least access to these documents and the  
23 ability to obtain them, and I think that's ultimately probably  
24 the question that would be the legal question.

25 We'd prefer it be done easily as opposed to, you

1 know, there could always be a corporate rep deposition of  
2 somebody. I mean, we're concerned if it takes a year,  
3 these -- you know, then we lag with those two parties, and  
4 then more discovery comes in later, it becomes somewhat  
5 staggered and it could become an issue at a later date. We  
6 don't know what's going to come from them so --

7 THE COURT: Do you know -- again, I don't know if  
8 you've had sufficient time to look at the documents -- if  
9 there are any categories of core documents that Hetero hasn't  
10 produced? My guess is the ANDA has been produced, but,  
11 obviously, the inspection reports are prepared and things of  
12 that sort.

13 MR. PAREKH: Your Honor, we have not seen any  
14 inspection reports for Hetero India. We have not seen  
15 communications between Hetero USA and Hetero India, nor would  
16 we expect to, given what was produced in core discovery.

17 We got some additional documents just last night that  
18 we have managed to load this morning but have not had a chance  
19 to review, so we don't know what's in that group.

20 But, in terms of the documents that we've seen so  
21 far, the ANDAs do not appear to be complete. They were  
22 produced in a -- in a manner that doesn't appear to be the way  
23 that the other defendants produced ANDAs in terms of they're  
24 not a cohesive -- it's not, you know, ANDAs starting with  
25 number one and going all the way down. It appears to be bits

1 and pieces, and we can't piece it together to know whether or  
2 not we have complete ANDAs.

3 THE COURT: Counsel for Hetero, let me ask you a  
4 question.

5 MS. POLETTTO: Yes, your Honor.

6 THE COURT: We started out a few moments ago with  
7 what the parties agreed to, and one of the agreements was that  
8 the defendants that we're talking about are going to give a  
9 list of all API manufacturing and finish facilities and a  
10 corporate relationship between at least the key defendants.  
11 Is your client going to do that? The one you represent.

12 MS. POLETTTO: My client, Hetero USA, has agreed to do  
13 that, yes.

14 THE COURT: Okay. So, in order to do that, won't you  
15 need to get information from this company in India?

16 MS. POLETTTO: No. My client, your Honor, has the  
17 information, but it's in the documents that we've produced.  
18 We have answers to those questions in the documents we've  
19 produced, which we can tell the plaintiffs, it's in the  
20 documents, but we can use those documents to make the  
21 representations as to what those facilities are. The  
22 corporate relationships is -- it's my client's understanding  
23 of those corporate relationships.

24 THE COURT REPORTER: I'm sorry, I can't hear you.

25 MS. POLETTTO: I'm sorry.

1           And as far as the corporate organizations, you know,  
2   that's in our corporate disclosures, and our client is aware  
3   of that.

4           THE COURT: Here is what I'm wrestling with, counsel.  
5   I would consider giving plaintiffs the right to take a  
6   30(b)(6) on these possession, custody, and control issues, the  
7   nuclear option. I don't want to do that. I really don't want  
8   to do that. I think it just takes us down a rabbit hole, and  
9   there's almost guaranteed to be disputes because it's such a  
10   factual determination. But, on the other hand, I don't want  
11   to wait nine or ten or eleven months for plaintiffs to get  
12   these core documents. Been in other cases like this, and  
13   clients make a strategic decision. I don't know what the  
14   facts are going to show. I don't know what the eventual  
15   ruling is. But when you look at the benefit or burden, yes,  
16   they're not served yet, but does it make sense from a  
17   strategic point of view for the client to say I don't want to  
18   risk some judge telling me that the American company has  
19   control over the foreign company, and this and other  
20   litigation for the rest of the century, we're going to have to  
21   produce foreign documents. Why not just produce them? A lot  
22   of companies do that.

23           MS. POLETTO: Understood, your Honor. This is a  
24   different situation. Perhaps a company that has different  
25   relationships in other situations, I don't understand. I

1 don't know specifically what you're referencing. It's just --  
2 it's not something that I can represent that we can do at this  
3 point in time.

4 THE COURT: What about Aurobindo?

5 MS. HEINZ: Jessica Heinz on behalf of Aurobindo USA  
6 and Aurolife LLC.

7 I might be stating the obvious here, but I think the  
8 Court is in a very bad position, and I think it's partially  
9 due to the fact that Hague service on these foreign companies  
10 wasn't initiated when suit was first filed against them. Had  
11 it been back in January, I don't think we would even be  
12 dealing with this situation right now, so I think that's  
13 something that's important to note.

14 And I also want to talk about how the plaintiffs are  
15 relying on -- I think they cited to a case that says the  
16 District Court of New Jersey follows this practical ability  
17 test when it comes to defining control, but from the case law  
18 that I've seen, it looks like the Third Circuit applies a more  
19 strict test in the case of, you know, Rule 34 discovery, which  
20 is called the legal rights test which basically says that the  
21 party has to have the legal right to obtain documents  
22 requested upon demand.

23 And it's my understanding from my client, you know,  
24 we're not just dealing with requests for documents owned by a  
25 foreign entity. This is a foreign party that we're talking

1 about, that they've chosen to bring into this litigation. And  
2 it's my understanding from my client that they can't get these  
3 documents from them. They won't give them to them. So I  
4 don't -- I mean, we can do discovery on discovery, but they're  
5 going to find out that they're not going to give them to us.

6 THE COURT: Do I take it Aurobindo has -- the U.S.  
7 company, whatever its name is, has produced core discovery?

8 MS. HEINZ: We have produced everything that we have,  
9 yes, and I have produced from Aurolife as well.

10 THE COURT: Is it too early for the plaintiffs to get  
11 their arms around what categories of core documents are  
12 missing?

13 MR. PAREKH: With Aurobindo, actually, they did  
14 produce full ANDAs, so that is different from the Hetero  
15 issue, and that was very helpful. We do also have FDA  
16 communications from Aurobindo. It's not -- we're not clear  
17 what is missing because it's hard to know what we don't have,  
18 but we do have more documents from Aurobindo than we do from  
19 Hetero in terms of categories.

20 MS. HEINZ: We have not turned over the DMF,  
21 obviously, because --

22 THE COURT REPORTER: Because? I can't hear you. I'm  
23 sorry.

24 MS. HEINZ: I'm sorry. We did not turn over -- we  
25 were asked what we didn't turn over. We didn't turn over the

1 DMF.

2 MR. HONIK: Your Honor, if I may, we would really  
3 relish the opportunity to create a factual record. I mean,  
4 many of the things we've seen in the public domain really  
5 support the idea that there is such control.

6 One only needs to go to Hetero's LinkedIn page, and  
7 this is what they've written about themselves. They write,  
8 and I quote: We have a significant presence in the  
9 development and marketing of finished dosages, active  
10 pharmaceutical ingredients, over-the-counter products.

11 It doesn't distinguish, it doesn't create a wall,  
12 legal or otherwise, between their finished dose operations and  
13 their API. And it has struck us that that wall really doesn't  
14 exist, and so we would really welcome the opportunity to  
15 conduct discovery in order to create that record and present  
16 it to the Court.

17 THE COURT: What would you request? A 30(b)(6)  
18 deposition?

19 MR. HONIK: Yes, your Honor.

20 THE COURT: Well, I'm going to grant that request.  
21 I'm going to draft an order. I just want Hetero and Aurobindo  
22 to know that the Court is doing this with the greatest of  
23 reluctance because this opens a door I do not want to open. I  
24 don't think it helps us advance the ball in the case. We go  
25 off on a tangent. Like I said, I have been in many other

1 cases where sophisticated clients weigh the risks and the  
2 benefits of voluntarily producing documents without prejudice.  
3 We can draft an order. But, again, I don't know how the Court  
4 is going to eventually rule on this, but the companies are  
5 running the risk that there is going to be an adverse  
6 decision, that may be forever binding in future cases, that  
7 they have to produce foreign documents. And that's -- some  
8 companies don't want to risk that. So, hopefully, they'll  
9 change their minds, but if not, we'll do what we have to do.  
10 We're not going to wait 10 or 11, 12 months to get these  
11 critical documents.

12 So I'll draft an order and give you the right to  
13 take, hopefully, limited discovery on the control issue, and  
14 then we'll set a briefing schedule and decide the issue.

15 Okay. Next issue?

16 MR. SLATER: The next issue is, again, a global  
17 issue. Your Honor, I'm referring to your order of April 24,  
18 2019, because this issue comes right from the language in the  
19 order.

20 THE COURT: This is the Core Discovery Order, right?

21 MR. SLATER: Correct.

22 THE COURT: I have it right here.

23 MR. SLATER: Your Honor, in Paragraph 5 on Page 2,  
24 your Honor directed the defendants to identify the Bates  
25 numbers of the documents responsive to each category of

1 documents listed in Paragraph 6 herein. And the --

2 THE COURT: That's pretty self- -- I don't know how I  
3 can make it any clearer.

4 MR. SLATER: I could tell you how.

5 THE COURT: (Laughs.)

6 MR. SLATER: No, I'm kidding -- I'm being -- I'm  
7 kidding.

8 Here is the dispute. Within Paragraph 6, you have  
9 Section 3, and there is multiple categories. There is  
10 Category 1, 2, 3, 4, all the way through Category 5, 6. And  
11 what the defendants have done is they produced the documents  
12 and said the communications with the FDA are in this range.  
13 And we said, well, can you tell us where the documents are  
14 that reflect each of the categories within there, 1 through 6,  
15 and we were told we don't have to do that; you figure it out.

16 So we're asking that they provide us the Bates  
17 ranges. For example, I will give you an important one,  
18 Section 3, efforts to contain, remove, or detect the  
19 contamination, so that we know what they're relying on as  
20 production of that information. It would be helpful for us to  
21 know what's been produced and what's not, as opposed to trying  
22 to figure it out for ourselves.

23 Because one of our concerns is there may be no  
24 documents responsive to Paragraph -- to Section 1 or Section  
25 2, but there may be 3, 4, and 5, and we don't know what they

1 have produced documents in response to, so we don't know if  
2 they answered all of these different sections, and we don't  
3 know what the documents correspond to.

4 THE COURT: Are we talking about a great volume of  
5 documents?

6 MR. SLATER: It's -- I can't given you the number of  
7 pages but it's -- it's somewhat significant. I mean, the  
8 overall production so far, compared to what we're ultimately  
9 going to get, is very small, so we're not talking about a lot  
10 of documents. There is really no great burden to doing this.  
11 Our view is it should have just been done in the beginning.  
12 And one of the things we said is we just want to make sure of  
13 what you've produced, what it's responsive to. And then, for  
14 example, with -- you know, testing is obviously a major focus  
15 for us, and we need to know which documents, which pages  
16 within there you're relying on as communication of test  
17 results. And we just don't have that, because, ultimately,  
18 one of the things we don't have, and -- we had asked in the  
19 meet and confer process, for example, can you tell us, A, a  
20 list of all the tests that have been done. We were told no,  
21 we're not doing that, that's not what was ordered. So then we  
22 said, well, can you at least tell us if the FDA communications  
23 that you've produced encompass all the testing that's been  
24 done relevant to this case? And we were told no, figure it  
25 out from the documents, and we don't need to tell you that.

1 So it left us in a bind, saying we at least need to know what  
2 you're saying you produced at this point so that when we do  
3 the, obviously, the general discovery, we ask for all the  
4 testing, we will be able to compare and see what's new because  
5 we obviously don't want to reanalyze the same data.

6 MR. HONIK: Your Honor, to give you a direct answer  
7 to your question, the size of the haystack of Category 3  
8 communications among all the defendants is about 10,000  
9 documents. 10,000. So you could see the dilemma of trying to  
10 discern, within the 10,000 or so documents, which fall into  
11 the six categories. If it was 20 documents, we wouldn't make  
12 this request, but that's a pretty big haystack. Pages. I  
13 misspoke. It's pages.

14 MR. GOLDBERG: Your Honor, I mean, I think one thing  
15 that all of the defendants did was identify -- when you look  
16 at your discovery order, identify the documents, by Bates  
17 range, by general category. The focus here is on 6(a)(3) and  
18 the subcategories. And one of the challenges to doing this  
19 the way they have asked is that within many of the documents  
20 that have been produced, you are going to have --

21 THE COURT: Multiple categories.

22 MR. GOLDBERG: And I'm holding examples.

23 THE COURT: I know.

24 MR. GOLDBERG: Right? And so we -- there is a, you  
25 know, there is a challenge here when plaintiffs are requesting

1 information, they want information, you order us to produce  
2 it, we produce it, we produce it quickly, we do what is, you  
3 know, reasonable and efficient, and plaintiffs want more  
4 guidance. I mean, they do have to review the documents.

5 Now, we don't want to make the judgment calls. It  
6 shouldn't be on us to determine, okay, this document is going  
7 to be listed as an ARB recall document and a communication  
8 document and a testing document. They're all there for us  
9 to -- certainly, for us to go back now and re-review, even if  
10 it's 10,000 pages or 20,000 or 30,000, is a significant  
11 burden. They have the information. And, you know, we have  
12 now told them we are going to provide them the lists that they  
13 requested. So, you know, given the lists and the general  
14 categories of information, there really isn't a lot of  
15 mystery.

16 THE COURT: The Court's intent when it drafted this  
17 order was for Category 1, 2, 3. The Court did not envision  
18 that Bates numbers would be -- in core discovery, would be  
19 given for 6(a)(3). So that's another way of saying  
20 plaintiffs' request is denied, to require the defendants to  
21 identify the Bates numbers specific to (3), (1) to (6). I  
22 assume they have identified the Bates numbers for (a), (1),  
23 (2), and (3).

24 MR. GOLDBERG: Correct, Your Honor.

25 THE COURT: That was the Court's intent when it

1 drafted the order.

2 Next issue?

3 MR. PAREKH: Your Honor --

4 THE COURT: Next general issue.

5 MR. PAREKH: The next general issue has to do with  
6 the format of the ANDA productions. And I mean, obviously,  
7 there was -- whether it was -- we don't think there was any  
8 intent on either side. This was an ambiguity. But it was our  
9 understanding that ANDAs, under the ESI protocol, are what  
10 would fall under the structured data provision of the ESI  
11 protocol, which would have required a meet and confer as to  
12 what format that they would be produced in. And the reason  
13 for that is that in the eCTD format, which is sent to the FDA,  
14 there are structure files which allow you to click through and  
15 find specific documents, know what was done through an index,  
16 and be able to tell, you know, what went into what category.

17 The way the defendants produced those documents was  
18 to break that structure and produce each of the files  
19 individually. The problem with that production is that at  
20 that point we can't recreate that structure, and --

21 THE COURT: Do you think the ANDA was produced in the  
22 format it was in in the usual course of business?

23 MR. PAREKH: They had to have because it's an FDA  
24 requirement that it be produced in eCTD format --

25 THE COURT: No, no.

1 MR. PAREKH: Oh, produced to us?

2 THE COURT: To you.

3 MR. PAREKH: No, absolutely not.

4 THE COURT: That's what I asked.

5 MR. PAREKH: No, it was not produced to us in the way  
6 it was kept in the ordinary course of business.

7 THE COURT: So we'll hear from the defendants, but is  
8 this just a matter of pushing a button and sending it out? Do  
9 you know -- we'll hear from the defendants -- will they have  
10 to go to any extra burden or expense to produce it in this  
11 format?

12 MR. PAREKH: What they should be able to do is copy  
13 the folder, as it was sent to the FDA, to either a hard drive  
14 or some other, you know, form, just copy it, paste -- you  
15 know, put it in there and produce it as a single Bates  
16 numbered document in its eCTD format. There should be no  
17 additional burden other than making that --

18 THE COURT: What's it called? eCTD?

19 MR. PAREKH: I'm sorry. It's a lower case "e,"  
20 capital "C," capital "T" as in Tom, capital "D" as in David.

21 THE COURT: Can someone speak for the defendants? Is  
22 this just a matter of pressing a button and producing it?

23 MR. TRISCHLER: Good afternoon, Your Honor. Clem  
24 Trischler.

25 Unfortunately, it's not, and if I could back up a

1 little bit. This issue was addressed with the Court at our  
2 June status conference.

3 THE COURT: The ANDA?

4 MR. TRISCHLER: Yes. We specifically asked what  
5 format the ANDA should be produced in, and what the plaintiffs  
6 indicated on the record at that time was they wanted the ANDA  
7 files produced in accordance with the ESI protocol. No one  
8 said at the plaintiffs' table at that point in time in June  
9 these documents are submitted to the FDA using the eCTD  
10 format, a format that the FDA has used for eight -- at least  
11 eight years, as far as I know. We want you to submit it the  
12 same way. No one ever said that. And so we went to the cost  
13 and expense of producing them in accordance with the ESI  
14 protocol which included, your Honor, a review, it included  
15 confidentiality designations to make those reviews, and we  
16 didn't -- we were mindful of the Court's directive that it's  
17 not going to sanction blanket confidentiality designations, so  
18 that meant reviewing and making certain that a document was,  
19 in fact, confidential. We redacted private patient  
20 information on bioequivalency studies, redacted patients'  
21 names.

22 If we have to go back and reproduce the ANDA files  
23 which each one -- in Mylan's case, we produced three ANDAs for  
24 valsartan-containing medications, each one over 20,000 pages  
25 in length. If we have to go back and produce them now in

1 another format, giving them the same documentation that they  
2 already have, we're going to have to do that same review over  
3 again. I've talked with -- I've checked with our vendor. The  
4 review process, the information that's been coded, will be  
5 lost. We have to do it over again. That's a significant  
6 expense, and I'm happy to represent to the Court that it's an  
7 attorney expense that my client has already incurred. It's  
8 tens of thousands of dollars.

9           The plaintiffs, at our meet-and-confer session today,  
10 understandably, they don't want to bear that expense, but my  
11 client shouldn't have to bear the expense of doing it twice.

12           And so the reality of it is, your Honor, they have  
13 the documents. They have the documents in accordance -- in a  
14 form that's in accordance with the ESI protocol that we all  
15 negotiated and that we all agreed to. And I wish it were as  
16 simple as pressing a button. If it were, I think it's one of  
17 those issues that we could have resolved this morning, but  
18 it's simply not, your Honor, and for that reason, we request  
19 that the plaintiffs' proposal be rejected. Where the ANDA  
20 files have been produced in accordance with the protocol  
21 negotiated by the parties, that ought to be enough.

22           MR. PAREKH: Your Honor, we believe that, one, the  
23 protocol talks about structured data being produced --

24           THE COURT: I'm sorry. What does "structured data"  
25 mean?

1 MR. PAREKH: Items that are kept in a structured  
2 format, for example, in a database or in a form which is where  
3 you have an index system which makes that underlying data  
4 usable. It's not just -- these aren't just Word documents  
5 that were in a folder. These were -- these were compiled in a  
6 very specific tabular way with information that tells you  
7 where things go, in what categories, which documents fit into  
8 which categories, and how to access them.

9 THE COURT: Is counsel correct that this was an issue  
10 that was discussed at a prior conference?

11 MR. PAREKH: It was not discussed directly. The way  
12 it was discussed was are you going to produce core discovery  
13 in conformance with the ESI protocol or not? They said they  
14 were not. We said no, we want it in conformance with the ESI  
15 protocol.

16 THE COURT: And I think I said --

17 MR. PAREKH: And you said produce it in the format --

18 THE COURT: With the ESI protocol.

19 MR. PAREKH: And the issue is whether they considered  
20 this structured data or whether they didn't, but they never  
21 talked to us about it.

22 THE COURT: But let me ask you a question. You know,  
23 you've been involved in these cases before. You know about  
24 ANDAs. You knew or should have known that this was the format  
25 that it was submitted to the FDA. Why did you not request

1 defendants -- why did you not tell defendants, hey, this is  
2 the format in which we want the ANDA production?

3 MR. PAREKH: Because we've never gotten it in any  
4 other format. It didn't strike me -- honestly, that they  
5 would produce it -- they would go to the trouble that they did  
6 of breaking it apart and producing it in a unusable format.  
7 It just -- it didn't strike me. It seemed like -- we've  
8 gotten it in eCTD format in every other litigation. We  
9 expected them to do -- if they were going to do something  
10 else, to meet and confer with us, because that's the format in  
11 which it's regularly kept.

12 As to Mr. Trischler's issue in terms of the burden  
13 that they have gone to and the burden that they will have to  
14 go to again, the only defendant that had any redactions on  
15 their ANDA is Mylan. And those redactions were limited to one  
16 specific type of a file which contained patient information.

17 THE COURT: Is that a discrete --

18 MR. PAREKH: It's a discrete item --

19 THE COURT: -- area that --

20 MR. PAREKH: Yes.

21 THE COURT: -- you'd expect someone who knows what  
22 they're doing can segregate out?

23 MR. PAREKH: Absolutely. They should be able to  
24 simply take that one folder of those documents and segregate  
25 those out and say, we're not going to produce them because

1 they're redacted documents and you already have them. We're  
2 okay with that. We don't have a problem with that. No other  
3 defendant that we have been able to tell has redacted any  
4 portion of their ANDA file, and, therefore, we don't believe  
5 that there is this huge additional burden --

6 THE COURT: Were any of the ANDA productions -- was  
7 there a privilege redaction?

8 MR. PAREKH: There were no privilege redactions other  
9 than the redactions for confidential patient information which  
10 are technically, I guess, not privilege redactions. The  
11 confidentiality designations can be done on the entire eCTD --

12 THE COURT: Of course.

13 MR. PAREKH: -- as it was done. There is no reason  
14 why that can't be done. So we don't believe that there is any  
15 significant additional burden for them to produce it in eCTD  
16 format.

17 Your Honor is absolutely right. If I had thought of  
18 it, I should have brought it up. You're right. But I didn't  
19 because I've never seen it done --

20 THE COURT: Is there any objection to designating the  
21 entirety of the ANDA as confidential? That's done in every  
22 one of my patent cases.

23 MR. PAREKH: No, there is no objection.

24 THE COURT: So, Mr. Trischler, right back at you.  
25 Counsel is saying, one, you don't have to do redactions again

1 because you don't even have to produce those documents again,  
2 and he's representing that there were no privilege redactions  
3 or assertions. So what's the burden?

4 MR. TRISCHLER: Well, your Honor, before I address  
5 the burden, let me address the issue of what was discussed.  
6 The discussion, and the record will speak for itself,  
7 obviously, but I have a vivid recollection of our June  
8 conference, and the discussion was not about how the core  
9 discovery production was going to be produced. We  
10 specifically raised the issue of how plaintiffs wanted the  
11 ANDAs produced, and this is what we were told to do, and we  
12 did. And the answer back from the plaintiffs was produce it  
13 pursuant to the ESI protocol, and your Honor agreed. And,  
14 again, the record will speak for itself, but I don't feel like  
15 I'm going out on a limb in making that representation to the  
16 Court.

17 As to -- as to the issue of burden, I understand the  
18 plaintiffs' suggestion now that the entire document can simply  
19 be marked as confidential. That's one thing. I don't know,  
20 and I'll confess I don't know the intricacies of the review  
21 process all that well to say that it's a simple fact of  
22 pulling out the pages -- identifying the pages and finding the  
23 pages where there is patient information that we feel that  
24 there is an obligation to redact that private information. I  
25 don't believe it to be that easy. I know how much time it

1 took us to conduct a review the first time. And, in  
2 committing -- in fulfilling my fiduciary obligation to my  
3 client, I would be hesitant to produce 60,000 pages of  
4 documents without reviewing them and just taking someone's  
5 word for it that it's been done the right way.

6 THE COURT: Here's what I'm going to do. I'm going  
7 to order, consistent with this Court's effort to take a  
8 practical view of the litigation and the issues, if plaintiff  
9 is representing that it's not in a usable format -- we're  
10 talking about a critical document in the case -- it just makes  
11 no sense. I'm going to order that the ANDAs be produced in  
12 this eCTD format -- you can meet and confer with the  
13 plaintiffs if you want redactions, et cetera -- with this  
14 proviso: Defendants, if you believe it's necessary and  
15 appropriate, you can make an application to the Court for  
16 costs, the extra costs that you're going to incur because of  
17 this new production. Do it by motion. If there is good  
18 cause, the motion is going to be granted. We'll hear from  
19 plaintiffs. And I think that's the fairest thing. I don't  
20 disagree that, in hindsight, plaintiff should have been more  
21 specific, but I think, as a practical matter, to advance the  
22 litigation, all documents, plaintiffs' and defendants', should  
23 be produced in the usual format, and it just sounds to me like  
24 it's just not a terribly complicated process. ANDAs are  
25 produced all the time in our patent cases. There is a rule,

1 it has to be automatically produced, and there is never ever a  
2 problem with privilege or such. And to the extent that there  
3 is any ambiguity, I'm saying you could mark one stamp  
4 confidential, the whole ANDA is confidential. Okay?

5 We're going to take a short break for this criminal  
6 procedure. It shouldn't take long. And then we'll get right  
7 back.

8 MR. SLATER: You need us to move from counsel table,  
9 right?

10 THE COURT: Yes.

11 (A recess was taken from 3:04 p.m. to 3:42 p.m.)

12 THE COURT: Counsel, you can come up.

13 Okay. Ready, counsel? We are back on the record.  
14 Thank you for your indulgence. Those criminal proceedings  
15 come up unexpectedly and there is nothing we can do about the  
16 interruption.

17 We dealt with -- in terms of disputes, we dealt with  
18 the control document issue, the Bates number issue, the eCTD  
19 issue.

20 Before we get onto any other disputes, the  
21 information that the defendants agreed to give to the  
22 plaintiffs, have you all agreed on a date when that's going to  
23 be exchanged?

24 MR. GOLDBERG: No, we did not.

25 THE COURT: Do you want to agree on a date so we

1 don't have a dispute in the future? 30 days?

2 MR. GOLDBERG: 30 days is fine, your Honor.

3 THE COURT: Okay. That's great.

4 Okay. Mr. Slater, any other generic, general macro  
5 disputes?

6 MR. SLATER: We do, and I'm going to -- our team is  
7 going to participate in that, defendant by defendant.

8 THE COURT: Wait a minute. Are we dealing specific  
9 defendant now or are we done with what I call the macro  
10 issues?

11 MR. SLATER: Oh, there actually is one -- there is  
12 one issue, you're correct. Our agreement on the lists didn't  
13 determine this one issue.

14 Your Honor, with regard to the productions, we have a  
15 disagreement. Again, it goes to the interpretation of your  
16 Honor's order from April. And the core discovery productions  
17 per Paragraph 2 concerned the facilities that manufactured the  
18 API used in valsartan or the facilities that manufactured the  
19 finished products. The defendants have taken the position  
20 that the productions only relate to facilities where the API  
21 was manufactured, despite the language of the order, so that's  
22 an issue we need your Honor to resolve for us, as to whether  
23 the productions are only from the API manufacturer facilities  
24 or from both.

25 MR. TRISCHLER: Your Honor, as part of -- Clem

1 Trischler again. I apologize.

2 As part of core discovery, the defendants produced --  
3 and we're talking about Subparagraph 5 of Paragraph 6(3) of  
4 your Honor's April order. The defendants produced  
5 correspondence with the FDA regarding 483s, Establishment  
6 Inspection Reports, CGMP reports and the like for the API  
7 manufacturing facilities, and that was based on the plain  
8 language of the Court's order which states that the production  
9 is -- should be with respect to "any facility that  
10 manufactured or supplied the API at issue."

11 What the plaintiffs have asked is that that be  
12 expanded to include not just the API facilities, but any  
13 facility that was responsible for the finished dose  
14 manufacturing of the product. We believe that's not core  
15 discovery. We believe it was not part of the order, and that  
16 what the plaintiffs are asking for now simply was not directed  
17 by the Court back in April which is the reason why it was not  
18 provided.

19 THE COURT: I think the defendants are right about  
20 this one. Paragraph 2 identified the defendants that were  
21 subject to the order. And Paragraph 6 in Sections (a) and (b)  
22 identified the specific documents for the two categories that  
23 have to be produced. And unless 6(a)(3)(5) is listed in 6(b),  
24 the finished product/dose manufacturer defendants don't have  
25 to produce it. And that appears to be the case, because, in

1 Paragraph 2, the Court referred specifically to 6(a)(3) and  
2 didn't list the other subnumbers of 6(a).

3 MR. PAREKH: So, just to be clear, the reason that we  
4 brought this up is our interpretation of 6(b)(2), where it  
5 referenced 6(a)(3), which is "Communications with the FDA,"  
6 was that it's those sub- -- those categories of documents --

7 THE COURT: That's right.

8 MR. PAREKH: -- and, therefore, it didn't really make  
9 sense where -- why would the finished product/dose  
10 manufacturer have to produce communications regarding the API?  
11 We simply thought that the Court was referring to those  
12 categories but replacing "finished dose manufacturer" with the  
13 "API manufacturer."

14 THE COURT: I take back what I said. I think I  
15 misinterpreted my order because the "3" that you just referred  
16 to is not in parentheses. It's a general "3." So since the  
17 Court referred to the general "3," 6(a)(3), specifically, in  
18 6(b), Mr. Trischler, tell me if I'm reading it wrong, but it  
19 seems pretty apparent that the communications in 6(a)(3) have  
20 to be produced by the finished product/dose manufacturer  
21 defendants. If you read it differently, I would like to hear  
22 your argument.

23 MR. TRISCHLER: I do read it differently, your Honor.  
24 My interpretation of that, and I think what we discussed is  
25 why the Court repeated for the finished dose manufacturers is

1 to try and address the issue of control. If you remember, we  
2 had a lot of discussion about producing documents if they were  
3 in your control. And so what 6(b)(3) is saying is that for a  
4 finished dose manufacturer, if you have these documents within  
5 your control, produce all the items in 6(a)(3), which include  
6 483s for the facilities where the API is manufactured. It  
7 wasn't to expand it.

8 To give you an example, my client has a manufacturing  
9 facility in West Virginia that produces a hundred different  
10 products. If there are warning letters that relate to all  
11 those different products, that wasn't what we wanted to get  
12 into with respect to core discovery. What we wanted to get  
13 into was the when, where, and how the problem with the API  
14 arose, and so, as I interpreted the order, and as I recall our  
15 discussions, what the Court was suggesting is we know that  
16 there are some defendants that aren't in the case yet, we know  
17 that there may be issues of control, so if we can't get to  
18 the -- all the foreign API suppliers, if there are finished  
19 dose suppliers in the United States that have control over  
20 these documents, then those finished dose suppliers, under  
21 6(b)(3), should produce the same categories of documents in  
22 6(a)(3). That's how I -- that's how I interpreted the order.  
23 I believe that's how the defendants interpreted the order.  
24 And I believe that interpretation to be entirely consistent  
25 with our dialogue and our argument concerning what should be

1 included within core discovery, and, again, to interpret it  
2 otherwise would lead to opening a Pandora's Box and requiring  
3 production at this very, very early stage of litigation of all  
4 things completely unrelated to what are the core issues in  
5 this case.

6 THE COURT: Doesn't 6(a)(3)(5) -- isn't that limited  
7 to facilities that manufactured or supplied the APA at  
8 issue -- API at issue?

9 MR. TRISCHLER: Yes, that's what we're saying, yes.

10 THE COURT: So you're saying 6(b) would only apply if  
11 an API manufacturer and supplier defendant did not produce the  
12 responsive documents?

13 MR. TRISCHLER: Yes, because it says -- if I look at  
14 6(b)(3), it says: "To the extent not produced by another  
15 responding" party, "the discovery listed in ... 6.a."

16 THE COURT: And the only facilities that would be  
17 subject to the production would be the facilities that  
18 manufactured or supplied the API at issue, not the facilities  
19 that made the finished product -- the finished product,  
20 period.

21 MR. TRISCHLER: Yes. That's our interpretation of  
22 the order, yes, sir.

23 THE COURT: Mr. Slater, counsel, anything different?

24 MR. SLATER: We just want to make sure we get it  
25 right.

1 THE COURT: Yes.

2 MR. SLATER: And it may be that Paragraph 5 is a  
3 separate entity unto itself as compared to the other -- I'm  
4 talking about Subparagraph 5.

5 Because, again, going to Paragraph 2 on the first  
6 page of your order, your Honor gave a blanket statement that  
7 this applies to -- shall produce core discovery concerning --  
8 not just -- it doesn't say concerning the defendants. It  
9 says, "concerning the facilities that manufactured the API  
10 used in Valsartan or the finished products at issue." So the  
11 order encompassed both categories of facilities.

12 Now, if Subparagraph (5) under 6(a)(3) is read by the  
13 Court to be limited to the facilities that actually  
14 manufactured or supplied the API, and it may even be that your  
15 Honor wants to tell the defense, and we probably wouldn't have  
16 an objection to that at the core discovery level, of limiting  
17 it to Valsartan-specific reports, I don't think that anybody  
18 would argue with that on our side because it's core discovery.  
19 So if with regard to the manufacturing facilities or the -- of  
20 either the API or the finished drug, everything else would  
21 apply, but Sub (5) would apply just to the API manufacturing  
22 facility, with regard to the Valsartan. I mean, that we could  
23 accept.

24 THE COURT: This is an example of no good deed goes  
25 unpunished.

1 MR. SLATER: Never.

2 THE COURT: The defendants, do I take it, only  
3 produced for the API manufacturing facilities?

4 MR. TRISCHLER: Yes. Yes, sir.

5 THE COURT: Okay. Let's limit it to that. In the  
6 next two to three months, we're going to be dealing with a  
7 document request, on a general basis, Rule 26 discovery, just  
8 put this in your document request and you'll get it, you know,  
9 reasonably soon, rather than making them go back -- if I rule  
10 that way, to go back. So I think that's a good, practical way  
11 to deal with this. For the time being, let's limit it to what  
12 the defendants have produced, and in your document requests,  
13 you could ask for whatever you want regarding the finished  
14 product/dose manufacturer facilities that may be at issue in  
15 this case.

16 MR. SLATER: Understood.

17 MR. PAREKH: Can we just get one clarification?  
18 Which is that the finished dose manufacturers did produce all  
19 of the remainder of 6(a)(3) with regard to the finished  
20 product/dose manufacturing. Because 5 is the only one that  
21 limits it to the API manufacturing facility. I just want  
22 there to be no ambiguity because Mr. Trischler referred to  
23 6(b)(3), which is -- and in the interpretation that  
24 Mr. Trischler took, it would make 6(b)(2) redundant, so we  
25 just want to make sure that the remainder of the items in

1 6(a)(3) were produced.

2 MR. TRISCHLER: And, your Honor, what I would  
3 indicate in response to that is with respect to -- with  
4 respect to Mylan, the answer is yes, everything -- all  
5 communications within all the other categories have been  
6 produced, and with the proviso of those defendants  
7 providing -- there are some defendants providing core  
8 discovery. As we know, we talked about Aurobindo, we talked  
9 about Hetero, that produced documents in their possession.  
10 You know, subject to that proviso, I think the answer to your  
11 question is yes.

12 MR. PAREKH: Thank you.

13 THE COURT: We're done with what I call the macro  
14 issues?

15 (No response.)

16 THE COURT: Okay. Are we going to go to the  
17 company-specific disputes now?

18 MR. SLATER: Yes, your Honor. And I think that as  
19 far as ZHP goes, I think we've resolved -- I think we've  
20 resolved the remaining issues. There are certain documents  
21 that ZHP is going to be providing us. There is a supplemental  
22 production of a design master file and -- a drug master file,  
23 excuse me -- and I think there's two inspection reports that  
24 are being provided as well, and I think we were told we would  
25 have that all by next Friday, so that -- we appreciate that.

1           And we just want to confirm one thing for the record.  
2       No production was made by ZHP. What we were told was that  
3       Princeton and Solco, the subsidiaries of ZHP, produced  
4       documents, and that those documents are the same documents  
5       that ZHP would have produced. Now, we just want to confirm or  
6       have defense counsel confirm for the record that anything ZHP  
7       has that would be responsive -- because that's obviously a  
8       very important API manufacturer in this case. To the extent  
9       they had any documents or have any documents that would be  
10      responsive to this order, they have all been produced through  
11      their U.S. subsidiaries. We just want to make sure there is  
12      no ambiguity on that, for obvious reasons.

13           MR. GOLDBERG: There is no ambiguity on that, your  
14      Honor. That's what we represented and that's what we did.

15           THE COURT: Next?

16           MR. PAREKH: So, we were able to resolve the  
17      Aurobindo issue --

18           THE COURT: Is that the next company --

19           MR. PAREKH: That is the next company on the list,  
20      your Honor.

21           I mean, other than the more general issue of whether  
22      or not they have to produce the Indian company documents,  
23      which we have already addressed.

24           THE COURT: That's the control issue.

25           MR. PAREKH: Control issue.

1           As to the Torrent defendants, we were again able to  
2 resolve --

3           THE COURT: Okay. Aurobindo is -- nothing to --

4           MR. PAREKH: No individual issues, your Honor.

5           THE COURT: Awesome.

6           Next is Torrent.

7           MR. PAREKH: Torrent is the next one. And this  
8 morning we were happy to be able to resolve the remainder of  
9 the Torrent issues.

10          THE COURT: Let's keep it going.

11          MR. PAREKH: The next one is the Teva defendants, and  
12 Ms. Goldenberg will deal with that one.

13          MS. GOLDENBERG: It's mostly good news for you, your  
14 Honor, on the Teva defendants.

15                Let's start with issue Number 2. On the ANDAs, I can  
16 confirm for the record that they will be supplementing their  
17 production and producing full copies of all ANDAs, both  
18 approved and not approved.

19                As to issue Number 3, Teva is also going to be  
20 supplementing its production, and I think they were going to  
21 talk over lunch and determine what date they could do that by,  
22 so I'll let them give you an update on that.

23                Issue number 4 was a global issue that we've already  
24 addressed here.

25                MS. WHITELEY: Can you identify the issues --

1 MR. SLATER: Slow down.

2 MS. GOLDENBERG: I'll be happy to. Yes.

3 All right. So issue Number 2 dealt with the full  
4 production of ANDA files. And, just to confirm for the  
5 record, Teva will be supplementing their production to ensure  
6 that we have full copies of all ANDA files, whether or not  
7 they were ultimately approved.

8 THE COURT: You said issue Number 2. Are you  
9 referring to Mr. Slater's August 6th letter?

10 MS. GOLDENBERG: Oh, sorry. I'm going off of  
11 Mr. Goldberg's letter.

12 THE COURT: Never mind.

13 MS. GOLDENBERG: And it's on Page 9 of his letter,  
14 just so we're all in the same spot. I figured out where you  
15 guys were going.

16 Okay. Issue 3 in Mr. Goldberg's letter, also on Page  
17 9, was a compilation of issues but, most notably, testing  
18 information. Teva has indicated that they will be  
19 supplementing their responses and, again, I think they'll  
20 provide the Court with the date on when they can do that by.  
21 But we don't have any disputes remaining on that issue.

22 Issue Number 4 was a global issue that's already been  
23 dealt with. That was the 483s, the inspection reports, that  
24 we have already discussed.

25 Issue Number 5, they have confirmed that they have

1 provided us with the full customer list for both recalled and  
2 non-recalled batches, so that means we're left with issue one,  
3 so four out of five we were able to take care of.

4           On issue one, there is a custodian whose name I'm  
5 going to try and pronounce correctly -- Constance Truemper,  
6 T-R-U-E-M-P-E-R. What we noticed in the production was that  
7 the files that were produced seemed to have a parent e-mail  
8 associated with them and that parent e-mail was not included  
9 in the production. It's our understanding that the reason  
10 that they haven't produced this was because the document was  
11 being sent from one person in-house to another person  
12 in-house, and when I say in-house, not to an attorney, just  
13 within the company. This just seems like a nitpicky issue for  
14 us. If there is a cover e-mail, we think it should be  
15 included. We don't know what it says, but it certainly, in  
16 theory, would talk about the document that was within the  
17 scope of the core discovery.

18           THE COURT: So is the argument that it's irrelevant,  
19 privileged, or --

20           MS. LOCKARD: Your Honor, Victoria Lockard.

21           The argument is that it's not within the scope of the  
22 Core Discovery Order. It is an internal e-mail. I fully  
23 anticipate this will be produced, as with the --

24           THE COURT: One document we're talking about?

25           MS. LOCKARD: No. Right now I believe they

1 identified 52 cover e-mails. These are e-mails from a person  
2 at Teva who circulated to a distribution saying, here's the  
3 submission to FDA, see attached. I mean, it's --

4 THE COURT: Why don't we just make this part of the  
5 Rule 26 discovery. It's not earth shattering and --

6 MS. GOLDENBERG: We can live with that.

7 THE COURT: We will deal with all those issues  
8 together.

9 MS. LOCKARD: Thank you. That was our proposal as  
10 well.

11 And I think I can represent we will be supplementing  
12 our production with the ANDA files which we are collecting and  
13 reviewing to make sure that, you know, to the extent we've  
14 left anything out, that that has been included.

15 And then on the testing issue, so the concern there  
16 is that there is testing that is ongoing, and it's just not  
17 complete, the response hasn't been submitted to FDA yet, but  
18 we've represented that we will supplement that once it is  
19 complete.

20 THE COURT: Good.

21 MS. LOCKARD: Okay. Thank you.

22 THE COURT: Are the plaintiffs getting the  
23 supplemental FDA correspondence that the Court ordered? There  
24 is an order that says without a request for production, you  
25 have to get correspondence sent to the FDA. Have you been

1 getting that?

2 MR. PAREKH: We have not seen a supplemental  
3 production that specifically references additional  
4 correspondence from the original production date. We don't  
5 know if there is any at this point because it's such a short  
6 time from the date the documents were produced to today. But,  
7 I mean, we would expect the defendants should be complying  
8 with that. We just -- we have not received any supplemental  
9 productions of that type of document.

10 THE COURT: That order just mirrors what's in the  
11 patent rules because I would assume, I don't know, that there  
12 is ongoing communications between the FDA and the defendants  
13 about this issue. So, rather than you making separate  
14 document requests or relying on 26(e), which most people don't  
15 pay attention to, unfortunately, just ordered it to be  
16 produced, so in due course, you'll get it.

17 MR. TRISCHLER: I can say, your Honor, on behalf of  
18 the defendants, we're certainly aware of that order and  
19 endeavor to comply with it. I know that for my client, for  
20 instance, there has been production of correspondence as  
21 recently as June and July.

22 THE COURT: Great.

23 MR. TRISCHLER: Now, practically speaking, we don't  
24 always -- I know there is a seven-day requirement. We don't  
25 always get them from our client as soon as things are sent,

1 but we're certainly aware of the supplementation order and  
2 we'll comply with it without additional requests as soon as we  
3 learn of the correspondence.

4 THE COURT: Okay. Who is next after Teva?

5 MR. PAREKH: Mylan is next, your Honor, and we have  
6 sort of one and a half topics left with Mylan.

7 The main topic is whether Mylan needs to produce  
8 their ANDA, which was -- has not yet been approved by the FDA  
9 regarding valsartan. And we understand defendants' position  
10 is that it only relates to ones that are subject to the issue  
11 underneath. However, there is definitely, from what we've  
12 been able to see publicly, as well as a few of the  
13 correspondence that were produced regarding that ANDA, that  
14 part of the reason why the FDA has not approved that ANDA has  
15 to do with the contamination issue. So, without seeing the  
16 ANDA, we can't simply say, well, there is nothing in there  
17 that would impact this case.

18 THE COURT: So you want it -- even though it hasn't  
19 been approved, you want it because?

20 MR. PAREKH: Because there may be items that are  
21 contained in that ANDA such as testing results or other, you  
22 know, documents associated with that ANDA that reflect Mylan's  
23 knowledge of the contamination issue or testing that was done  
24 by Mylan regarding those issues.

25 THE COURT: Is that type of -- I guess it's an

1 application not yet approved within the scope of the core  
2 discovery?

3 MR. PAREKH: The Core Discovery Order does not  
4 distinguish between approved and unapproved applications.

5 THE COURT: I think the Court's intent was approved  
6 ANDA files. If you want to make a request under Rule 26,  
7 that's appropriate. We'll see if there is an objection. But  
8 the Court's intent was just the approved ANDA files.

9 MR. PAREKH: The reason why we believe that it's  
10 relevant is because there were inspections of facilities at  
11 Mylan.

12 THE COURT: I'm not ruling whether it was relevant or  
13 not. I'm just saying it's not within what the Court intended  
14 core discovery to be. That's all. So you have every right in  
15 the world to ask for it under Rule 26, which we're going to  
16 deal with in the next couple of months, and if Mylan objects,  
17 we'll deal with the relevancy issue.

18 MR. PAREKH: And then the other half of the -- the  
19 half sort of dispute is that Mylan has produced a list of  
20 customers, but only as to the specific recalled lots, and the  
21 issue is we believe that that should be produced back to 2012.  
22 There are no other defendants who have taken the position that  
23 it only is effective as to recalled lots. Mylan is the only  
24 one with that position.

25 THE COURT: Let me just take a look at the order real

1 quick.

2 MR. TRISCHLER: Your Honor, I don't want to interrupt  
3 your reading, but I don't think we have much of a disagreement  
4 because what we -- what we agreed to do as part of our meet  
5 and confer today is the Mylan defendants have already provided  
6 a list of API customers; we've provided, as part of the core  
7 discovery, a list of customers known to have received finished  
8 dose products subject to the recall; and what we discussed  
9 today was part of our concern with -- with respect to the  
10 order is I'm not aware of a list per se that would identify  
11 every customer going back to 2012, but what I indicated to the  
12 plaintiff that we would -- plaintiffs that we would endeavor  
13 to do is that I would go back to my client and try to identify  
14 all known distributors from 2012 to present. So we're willing  
15 to work on that. That's what we had talked about. I thought  
16 we had resolved -- agreed on that, but we wanted to put it on  
17 the record. That was sort of the one and a half items. But  
18 perhaps I'm misstating something.

19 MR. PAREKH: No, I think you're correct. It's just  
20 my note did not reflect that. But yes, that was the  
21 agreement, and that is -- we put it on the record. We're done  
22 on that one.

23 THE COURT: Good.

24 MR. PAREKH: The next defendant is Hetero U.S.A.  
25 They made a production last night. We are hopeful that that

1 production resolves all issues, but because we haven't been  
2 able to review it, that's the best representation that we can  
3 make on that one.

4 THE COURT: So you have leave to raise the issue with  
5 the Court at a future conference since you didn't get the  
6 documents on a timely basis.

7 MR. PAREKH: Okay. And I believe that concludes all  
8 the individual defendants, your Honor.

9 THE COURT: Are there any insurance issues?

10 MR. PAREKH: Ms. Goldenberg is going to address  
11 those, your Honor.

12 MS. GOLDENBERG: I think most of this, your Honor, is  
13 just going to be putting on the record that we have agreed to  
14 a great deal, but I want to recap and make sure there are no  
15 disagreements from the other side.

16 So, my understanding is that -- let's see -- Hetero  
17 Labs has not produced an insurance policy. Hetero USA,  
18 however, has agreed to produce their insurance policy. And we  
19 have already discussed the reasons that Hetero Labs is not  
20 willing to make productions at this point, because they  
21 haven't been served.

22 Additionally, the -- let's see -- the Mylan entities  
23 have sent complete insurance disclosures, so I think we're  
24 good on that front.

25 ZHP has responded that they have no insurance, and

1 the Solco, Princeton, Huahai entities have sent complete  
2 insurance productions.

3           The Teva, Aurobindo, and Torrent entities have all  
4 produced insurance policies, and they informed us earlier  
5 today that those productions were all complete, so I believe  
6 that those are fine. The only caveat is that they are  
7 checking to find out if those are claims made policies,  
8 because they only go back to 2017. As long as we get  
9 clarification on that issue, I don't think that we have a  
10 problem, but for now, we're just waiting for them to check on  
11 that issue and get back to us.

12           And I think if someone from defense can just provide  
13 reassurance on the record that we do have all of the insurance  
14 policies and that I have stated everything correctly, that  
15 would be helpful, but I think I've got it all right.

16           MS. LOCKARD: Just on behalf of Teva, I believe  
17 that's accurately stated, that we've produced all of the  
18 insurance policies. We are checking to confirm our belief  
19 that they are claims made, and if it's other than we believe,  
20 we'll let Ms. Goldenberg know.

21           MS. GOLDENBERG: Okay. And I believe that all of the  
22 entities, with the exception of Hetero, have produced  
23 reservation of rights letters, to the extent that they have  
24 received them. And the defendants agreed earlier during our  
25 meet and confer that if any of those arose in the future, that

1 they would be willing to pass those along.

2 THE COURT: So you haven't received any disclaimer  
3 letters yet?

4 MS. GOLDENBERG: I don't think so. So I guess that's  
5 a long way of saying that I think we're fine.

6 THE COURT: Okay. So, as long as we're together, are  
7 there any other issues that we need to address? We always  
8 start with the plaintiff, then we'll go to the defendant.

9 MR. TRISCHLER: Right. I think we're going to talk  
10 about the same thing.

11 MR. SLATER: Yeah. We've discussed, if the Court  
12 will approve it, modifying the schedule for us to serve our  
13 document requests. In part, that's been necessary because the  
14 documents are rolling in and we're still reviewing them, and  
15 part of it is just the time of year.

16 THE COURT: Just give me the dates.

17 MR. SLATER: We would like to be able to serve our  
18 document requests by the end of the month, August 30th. And  
19 then counsel told us in the hall they wanted to talk to your  
20 Honor and float a different date to provide objections because  
21 of their needs, and we don't have an objection to the date  
22 that they suggested but --

23 THE COURT: Let me get out my schedule.

24 MR. SLATER: -- I just don't know if it's going to  
25 run into the October 24 date.

1 THE COURT: We'll work this out.

2 So the current date -- okay. So plaintiff, we moved  
3 that back 15 days. When did defendants want to object?

4 MR. TRISCHLER: Well, we had proposed 90 days. And  
5 plaintiffs did not commit --

6 THE COURT: We're not talking about answers. We're  
7 just talking about objections, just objections.

8 MR. TRISCHLER: I understand, your Honor. What --  
9 the position -- you know, without having seen the requests,  
10 our concern was that when we get the requests, it's difficult  
11 to formulate objections in a vacuum. I believe we have to see  
12 the documents, understand what our client has or doesn't have.  
13 For instance, how do you formulate an objection to  
14 burdensomeness until you talk to people and get information  
15 about what's available? So we certainly don't want to file  
16 boilerplate objections. That could be done in 30 days. We're  
17 hoping to do better than that. And so --

18 THE COURT: Let's make it 45 days. Okay? So that  
19 takes us to October 15th.

20 MR. GOLDBERG: Your Honor, if I may, I just want to  
21 remind the Court that for some defendants, you're talking  
22 about definitely four different sets of document requests  
23 going to four different parties. So, you know --

24 THE COURT: Because you represent four companies?

25 MR. GOLDBERG: Correct. And so we're going to be

1 responding on behalf of ZHP, which the document requests will  
2 look different, because they're going to be API focused and  
3 they're going to be China focused. We're going to have  
4 Princeton, the distributor. We're going to have a finished  
5 dose manufacturer response. We need to craft -- what we're  
6 trying to do is avoid boilerplate objections to the extent we  
7 can.

8 THE COURT: Here is what I think you should do, just  
9 like we always do. 45 days. When we get closer to the  
10 deadline, if there is good cause to extend the dates, you know  
11 they're going to be extended. If we start at 90 days, we're  
12 going to be six months down the road. So if there is good  
13 cause, there is a good reason to extend the deadlines, we  
14 will, but we're not talking about responses. We're talking  
15 about objections.

16 MR. GOLDBERG: Right. And what we want to do is be  
17 able to provide objections that have meaning.

18 THE COURT: Of course.

19 MR. GOLDBERG: And so, avoiding the natural response,  
20 which is, your Honor, this is just a boilerplate objection,  
21 you should overrule it.

22 THE COURT: You can do that in one week.

23 MR. GOLDBERG: Right, of course we could do that. So  
24 we're really trying -- this is not going to be -- A, it's not  
25 going to be a small number of document requests. I guarantee

1 that you're talking, you know, if not around a hundred, more  
2 than a hundred for each of these kinds of defendants. Just  
3 drafting alone is going to take time. So ...

4 THE COURT: Okay. Document requests are due August  
5 30. Objections are due October 15th. Then we'll give the  
6 parties 45 days to meet and confer. And then we'll have, I  
7 guess, our conference in December sometime to resolve all  
8 discovery disputes. It will be set sometime in December,  
9 which means that we will have to reschedule -- the current  
10 date for the conference to address the disputes is October  
11 23rd, so we'll move that back to December. But if we keep on  
12 extending all these deadlines, we'll never get done with this  
13 case. So, to me, this is always the most time-intensive  
14 effort in the case, and once we get through the documents and  
15 ESI, things usually go pretty smoothly, so I really want to  
16 get through this.

17 So I'll draft an order summarizing what we discussed.  
18 I hope Hetero and Aurobindo will reconsider their positions so  
19 we don't have to get into the 30(b)(6) deps issue but, if not,  
20 we'll do what we have to do.

21 Over the next couple of months, I guess we'll be  
22 working on -- you'll be working on your objections. We'll  
23 finalize all the fact sheets. The answers will start to be  
24 rolling in. Okay?

25 MR. SLATER: There is only one other thing to just

1 touch base on, which we've discussed as well with counsel, and  
2 we discussed it with the Court the last time we were here, I  
3 believe. We would like to start a meet-and-confer process  
4 with the defense regarding custodians and search terms. And I  
5 think that we really need to start to get some dates on the  
6 calendar in September to start to informally exchange -- you  
7 know, the documents we have are so -- because they're core, we  
8 don't really have a good visibility into who the people are  
9 that are going to matter. It just doesn't come from these  
10 documents. There is a few names on them, but those are really  
11 the people who are just corresponding with the FDA, so we have  
12 some regulatory names. But we really need to start to have a  
13 robust discussion and a frank off-the-record discussion, we  
14 would suggest as we did in Benicar, regarding who are the  
15 people that matter, what are the different departments, what  
16 are they called, what are the documents referred to as, what  
17 are we -- you know, what do we need so that we can start to  
18 formulate the search terms and the custodian list so we can  
19 get that teed up with the Court as well, you know, this fall.  
20 So we just would like to just start to be able to meet and,  
21 again, we would appreciate the opportunity, once we have some  
22 exchange of -- on a preliminary and foundational level with  
23 defense counsel, to -- again, to avoid a 30(b)(6) deposition,  
24 as the Court had us do in Benicar, we were perfectly fine  
25 doing it again, to sit down with knowledgeable witnesses from

1 the companies and talk --

2 THE COURT: But they weren't taken in Benicar, were  
3 they?

4 MR. SLATER: No. What I'm saying is we had asked for  
5 it, and your Honor said no, no, you'll meet with them  
6 informally, and it worked very well where they brought in  
7 knowledgeable -- off-the-record conversations, but  
8 knowledgeable corporate people who talked to us and told us  
9 these are the people that matter, these are the departments,  
10 here is how it worked --

11 THE COURT: I think your discussion is a good one.  
12 We're not going to wait -- we can't wait until December to get  
13 the custodians and search terms. We can't wait until the  
14 ESI -- well, obviously, it has to be done before the ESI and  
15 documents are produced. But there is no way we're starting  
16 this process in December to identify custodians and search  
17 terms. So what suggestions do you have, defendants, about how  
18 to move this along?

19 MR. GOLDBERG: I thought we had discussed this at the  
20 last conference. This very issue about interviews was raised.  
21 What we had discussed was that defendants would put together a  
22 proposed custodian list, that -- we actually didn't decide who  
23 would put together a first list of search terms. That we  
24 didn't actually --

25 THE COURT: Did you talk about timing? I don't

1 remember.

2 MR. GOLDBERG: No, we didn't talk about timing,  
3 except to say that we would -- that what happened in Benicar  
4 with respect to interviewing witnesses about this was  
5 something that happened at the end of a process. We don't  
6 think it is the first step in the process. And so what we  
7 thought would be something more along the lines that we would  
8 propose a list of custodians. They now have enough discovery  
9 to react to it. There can be some process there. It may be  
10 that we avoid burdening a person from coming to the court to  
11 talk about these issues among the parties. And that, you  
12 know, that can be in September and October. That can be as  
13 we're dealing with the ESI.

14 I mean, I think -- in light of what we've done, I  
15 think it would be fair to have them make a first list of ESI  
16 search terms but -- and we can do the list of custodians and  
17 go from there over the next, you know, four weeks, six weeks,  
18 and see where we get to.

19 MR. SLATER: We have no problem with defense counsel  
20 sending us a first list of custodians and why they matter. I  
21 mean, I'm sure they can provide that to us, you know, fairly  
22 quickly. We can start to formulate a list of search terms,  
23 but we don't have -- we have some documents but we don't have  
24 a lot, so there is going to be -- there is a knowledge gap at  
25 our end. But what we don't want to ultimately do is --

1 because it's just not practical -- is have a back-and-forth  
2 discussion between attorneys to get the information we need to  
3 define the right custodians, et cetera, because it just -- you  
4 need to be able to talk to somebody in the company and have  
5 more of a transparent discussion. Otherwise, we'll be in  
6 December, as your Honor said, or January, and that's not what  
7 anybody wants. I mean, I don't think we're saying entirely a  
8 different thing, but I think it has to be understood we're  
9 going to be able to get this information directly from someone  
10 from the company in informal, off-the-record discussions  
11 because, again, we're bypassing the 30(b)(6) process. Your  
12 Honor made it very clear how you wanted to do this, and we're  
13 perfectly fine with that, so we're not objecting to that. But  
14 we have to be able to talk to someone from the company  
15 directly and be able to have a -- more of an organic  
16 conversation where the person gives an answer -- oh, well,  
17 what does that mean? Oh, what about this? And that's how we  
18 learned what we needed to know. And, again, we only had to  
19 add, I think, one or two custodians in that other litigation,  
20 towards the end, and it was just because certain documents  
21 came out late in the process and one or two people became  
22 relevant.

23 MR. GOLDBERG: Just on the ESI protocol or on the  
24 search terms, what we can do is when you give us your document  
25 requests, we'll put out the first set of search terms since

1 you don't have the kind of documents you think would give you  
2 that, we'll respond in connection with the document requests.  
3 That may be the best thing to do. In terms of -- you know, we  
4 haven't crossed the bridge in this case yet whether 30(b)(6)  
5 depositions or informal interviews, that issue hasn't  
6 been handled --

7 THE COURT: No, it hasn't.

8 MR. GOLDBERG: I mean, we're trying to propose a  
9 process where we can hopefully avoid even getting to that  
10 bridge.

11 THE COURT: We may differ on this, but it seems to me  
12 that a defendant should take the first cut at the custodians  
13 and the plaintiffs should take the first cut at the search  
14 terms.

15 MR. SLATER: That's fine.

16 THE COURT: Because you know what you're looking for.

17 MR. SLATER: We have some idea.

18 And then, also, it may be helpful -- we're obviously  
19 going to ask for a lot of different corporate organizational  
20 charts in a formal way in the discovery requests. It would be  
21 helpful, when they provide us the proposed custodians, to  
22 provide those work charts that they do have, or at least  
23 something that lays out how the company --

24 THE COURT: Internal, as opposed to what you have  
25 agreed to exchange, sort of the corporate-wide organization?

1           MR. SLATER: Correct, correct. And we are obviously  
2 going to formally request things, you know, like corporate  
3 organization of the company and then -- you know, in different  
4 departments, medical affairs or clinical affairs, you know,  
5 the different quality assurance departments, all the  
6 departments that we relate, but to the extent they have that  
7 information, it may not be something we have to wait for the  
8 discovery requests to be formalized before we get that. We  
9 would just ask that they start giving that to us because,  
10 again, then we can understand what is it that we're looking  
11 for, what's the vocabulary of the different departments, and  
12 then when we do finally get to the point of being able to have  
13 a candid interaction, we can say, well, you know, what did  
14 this department do? Was testing done by this department? Who  
15 were the people in charge? Who were doing the inspections?  
16 Who were -- you know, who were crystallizing -- the obvious  
17 questions, and we can at least understand the structure that  
18 we're discussing.

19           THE COURT: Let me ask you a question. At least for  
20 the moment, are we dealing with the two categories of  
21 defendants that were identified in the Core Discovery Order?  
22 We're not waiving any right to take discovery -- document  
23 requests regarding the wholesalers, retailers, those people,  
24 but are we focussing on those two categories, the API people  
25 and the finished product people?

1 MR. SLATER: I actually hadn't really thought about  
2 that. I thought we were doing everything. But it makes  
3 sense, it makes sense to start at that level --

4 THE COURT: Yes. I don't disagree.

5 MR. SLATER: -- and then go to the next level. And I  
6 think what we're going to learn through this interaction over  
7 the next several months is -- like one of the things we're  
8 asking for, and we discussed out in the hall, is supply chain,  
9 which we talked about earlier, and your Honor said, well, then  
10 we're going to see from ZHP where did everything flow and what  
11 are the different chains all the way down to somebody's --

12 THE COURT: Aren't you going to get that?

13 MR. SLATER: We're eventually going to get that, so  
14 that help us as well to understand, and then we'll know what  
15 we want to ask of each defendant, so we have no problem with  
16 that.

17 THE COURT: So what about, say, you -- what about if  
18 you each exchange your first cut at a custodian and search  
19 terms list September 15th, and then meet and confer, and we'll  
20 see where we are on October 15th?

21 MR. SLATER: That's acceptable to us, your Honor.

22 THE COURT: Because doesn't it have to be finalized  
23 by December? Assuming in December we're going to resolve all  
24 discovery disputes regarding the Rule 26 ESI and document  
25 requests. Then you'll have a set, give it to the client, say

1 this is what we have to respond to. That's the deadline for  
2 finalizing the custodian and search term list, right? But it  
3 is a very labor intensive effort, so if we start in September,  
4 we should be done by December.

5 MR. SLATER: It's the only way we'll get it done.  
6 And I'll just put this over to the side. We're talking about  
7 in the English language at this point. Because, obviously,  
8 there is probably going to be a need at some point to deal  
9 with the Chinese language but --

10 THE COURT: Absolutely. I would think so.

11 MR. SLATER: -- we can -- that's something we can  
12 learn, hopefully, through the meet-and-confer process, to find  
13 out what documents are kept in Chinese, what are in English,  
14 et cetera, so we can figure out what it is we're asking for  
15 and what we need, when we get to that point, in terms of  
16 search terms in a foreign language.

17 THE COURT: Defendants, can we live with that?

18 MR. GOLDBERG: Yes, your Honor.

19 THE COURT: September 16, I'll put this in the order,  
20 defendants take the first cut at the custodians. I guess it  
21 would be for each of the responsive defendants. Plaintiffs  
22 take the first cut at search terms. I guess it would be by  
23 category, right? And then 30 days or so to give comments,  
24 meet and confer, and then we'll build in times to meet with  
25 the Court, with the goal of getting it finalized in hopefully

1 December, and then away you go.

2 MR. GOLDBERG: And this is at the API and finished  
3 dose level?

4 THE COURT: Yes, I think so.

5 I have a feeling, hopefully, that when all of this is  
6 straightened out and the dust settles, you'll say, well, we  
7 need this category of documents from the distributor or  
8 wholesaler, and you may need one or two categories, but I  
9 would hope you wouldn't need an omnibus document request from  
10 those sort of peripheral people.

11 MR. SLATER: Yeah. The only caveat -- you're right,  
12 your Honor, with just one caveat. We may need to come back to  
13 your Honor if we have an issue with defense, which we hope we  
14 won't. There may be certain things we need from some of the  
15 other categories of defendants that may relate to some of the  
16 economic claims, pricing, some of the class issues --

17 THE COURT: I agree with you. I don't disagree with  
18 you, but that's not a front burner issue right now.

19 MR. SLATER: When that becomes -- when we start to  
20 see those issues, we'll will talk to the defendants.

21 THE COURT: No, I agree with you. You'll need to do  
22 your economic model and you'll seed sales and pricing  
23 information, and that's when it will come into the forefront,  
24 but we've got enough to do before we get there.

25 MR. SLATER: And we're hopeful, frankly, that the

1 finished dose manufacturers will have most of that  
2 information, if not all of that information, anyway.  
3 Presumably, they know what the drugs are being sold for, but  
4 there may be gaps. So we'll seek it in the first instance,  
5 obviously, from them.

6 THE COURT: Okay. Anything else, counsel?

7 MR. GOLDBERG: Nothing from the defense, your Honor.

8 MR. SLATER: Just one last thing. The things that we  
9 said there is going to be followup, certain -- I know  
10 Mr. Goldberg gave us deadlines that he's going to produce  
11 certain things, but just overall, just in terms of some of the  
12 things that are being provided that we put on the record, I  
13 thought maybe it would make sense just to say when will that  
14 be produced by, just so it's not hanging out there.

15 THE COURT: Well, everything you agreed -- you  
16 started out by listing the three things you agreed on. We  
17 said that's going to be produced in 30 days.

18 MR. SLATER: Right.

19 THE COURT: And then the eCTD, I don't know how long  
20 that takes, but we'll probably do 30 days.

21 MR. SLATER: Frankly, your Honor, we're fine with an  
22 outside of 30 days, if the defense is fine with it.

23 THE COURT: Yes.

24 MR. SLATER: Other than I think there was a couple  
25 things that ZHP said they would give us within, you know,

1 about a week and a half, but other than that, as long as there  
2 is some deadline, that's fine.

3 THE COURT: Yes, if they agree to do it earlier, of  
4 course we're not going to object to that.

5 You have the extension for the document requests and  
6 the objections. We talked about custodians and search terms.

7 I don't think we have a call for the end of August,  
8 but if an issue comes up, we're available.

9 I think our next in-person meeting is the -- well,  
10 the next in-person meeting is the end of September, but we'll  
11 have a phone call, unless we need to meet in person, in mid  
12 September. And I hope everybody enjoys the rest of their  
13 summer.

14 RESPONSE: Thank you, your Honor.

15 (The proceedings concluded at 4:34 p.m.)

16 - - - - -

17  
18 I certify that the foregoing is a correct transcript  
19 from the record of proceedings in the above-entitled matter.

20

21 /S/ Carol Farrell, NJ-CRCR, FCRR, RDR, CRR, RMR, CRC, CRI  
22 Court Reporter/Transcriber

23

24 September 05, 2019  
25 Date

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